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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,431	08/29/2001	Nathaniel Milton	342312003601	7457

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EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 01/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,431	MILTON ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1-21, drawn to a parental formulation.

2. Claims 22-30, drawn to a freeze-dried formulation.

3. Claims 31-36, drawn to a parental formulation that comprises an aqueous solvent and a freeze-dried formulation.

4. Claims 37-39, drawn to a process for preparing a parental formulation.

5. Claims 40-42, drawn to a process for preparing a freeze-dried formulation.

6. Claims 43-45, drawn to a process for preparing a freeze-dried formulation.

7. Claim 46, drawn to a formulation that comprises an aqueous solvent and a freeze-dried formulation.

8. Claims 47 and 49, drawn to a parental formulation which does <u>not</u> contain any water.

9. Claims 47-49, drawn to a parental formulation which <u>does</u> contain water.

10. Claim 50, drawn to a method of using the formulation of claim 1.

11. Claim 51, drawn to a method of using the formulation of claim 31.

12. Claim 52, drawn to a method of using the formulation of claim 46.

The claimed inventions are distinct.

Groups {1, 3, 7} and {10, 11, 12} are related as product and process of use. The inventions

can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). However, in the event that any of Groups 1, 3 or 7 is elected, and claims therein found allowable, the corresponding method-of-use claims will be rejoined therewith for further examination.

Groups 1-3 and 7-9 are drawn to formulations, and Groups 4-6 are each drawn to a process of making a formulation. However, it is not the case that Groups {1-3, 7-9} and {4-6} are related as product and process of making. Consider, for example, claims 22 and 40. First, claim 22 requires a bulking agent, which is not suggested by claim 40. Second, claim 40 permits a carbohydrate to be present, which is not suggested by claim 22. Claim 22, of course, does not preclude carbohydrates; but a search for carbohydrates (in combination with the other limitations) is not necessarily going to be required in the case of claim 22. Third, claim 22 requires that the surfactant is present in an amount greater than 5% (w/w). It is unclear, however, exactly what the surfactant concentration would be in the case of claim 40, after freeze drying has occurred. It may be, for example, that dissolution of an echinocandin can be made to occur when 3.3 mg of echinocandin is placed in (a final volume of) 10 mL of 1% surfactant, in which case the surfactant will be present in the freeze dried formulation at a level below 5%. Another difference is that claim 40 mandates a

filtering step; the formulation of claim 22 could be prepared without such. Another difference is that claim 22 permits a salt of an echinocandin to be used, whereas this is not suggested by claim 40. Thus, there are a number of distinctions between claims 22 and 40.

Consider next claim 37 versus claim 1. One difference is that of the carbohydrate complex recited in claim 37. But apart from that, there is the question of other ways of making the formulation of claim 1. For example, one could prepare a freeze-dried formulation first, and subsequently reconstitute with an aqueous vehicle. Or perhaps one could filter the formulation, a process which is not required or suggested by claim 37.

Claim 47 has been bisected into two groups. Claim 47 encompasses an anhydrous formulation, but it also encompasses an aqueous formulation. Clearly, the properties (between the two) will differ, and one is not necessarily obvious over the other.

Notwithstanding the foregoing, in the event that applicants elect a group that is drawn to a formulation *per se* (not to a method of making it), and claims therein found allowable, claims that are drawn to a method of making that formulation will be rejoined for further examination (or allowance). Additional rejoining beyond that will be considered depending on what agreement is reached as to what is novel and what is obvious.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one

claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

- In the event that Group 1 is chosen for initial examination, the species to be elected are the following:

  (a) a specific echinocandin, with a fully defined structure;

  (b) a specific surfactant;

  (c) a specific concentration of the surfactant;

(d) a statement as to whether a stabilizing agent is required or not required. If required, what is the identity of the agent (e.g., mannitol, His, Lys, sucrose, lactose)…?

(e) a statement as to whether a buffer is required or not required. If required, what is the identity of the buffer (e.g., acetate, citrate, tartrate)…?;

(f) a statement as to whether a tonicity agent is required or not required. If required, what is the identity of the agent (e.g., glycerin, lactose, mannitol) …?

- In the event that Group 2 is chosen for initial examination, the species to be elected are the following:

(a) a specific echinocandin, with a fully defined structure;

(b) a specific surfactant;

(c) a specific bulking agent;

(d) a specific concentration of the surfactant.

- In the event that Group 3 is chosen for initial examination, the species to be elected are the following:

(a) a specific echinocandin, with a fully defined structure;

(b) a specific surfactant;

(c) a specific bulking agent;

(d) a specific concentration of the surfactant;

(e) a statement as to whether a stabilizing agent is required or not required. If required, what is the identity of the agent (e.g., mannitol, His, Lys, sucrose, lactose)…?

(f) a statement as to whether a buffer is required or not required. If required, what is the identity of the buffer (e.g., acetate, citrate, tartrate)…?;

- In the event that Group 4 or 5 is chosen for initial examination, the species to be elected are the following:

(a) a specific echinocandin, with a fully defined structure;

(b) a specific surfactant;

(c) a statement as to whether a carbohydrate must be present, and if so, what is the carbohydrate?

- In the event that any of Groups 6-9 is chosen for initial examination, the species to be elected are the following:

(a) a specific echinocandin, with a fully defined structure;

(b) a specific surfactant;

(c) a statement as to whether a carbohydrate must be present, and if so, what is the carbohydrate?

(d) a statement as to whether a stabilizing agent is required or not required. If required, what is the identity of the agent (e.g., mannitol, His, Lys, sucrose, lactose)…?

(e) a specific buffer (e.g., acetate, citrate, tartrate);

(f) a statement as to whether a tonicity agent is required or not required. If required, what is the identity of the agent (e.g., glycerin, lactose, mannitol) …?

(g) a statement as to whether a bulking agent is required (or not), and if required, what is the identity of the agent?

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at 571-272-0951. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600